REMARKS

The office action of April 17, 2006 and the communication of September 19, 2006 have been reviewed and their contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 22-25 and 28-36 remain in this case, claim 36 being added in the present response. No new matter has been introduced by this amendment. New claim 36 is supported by paragraph [0014] of the published application.

As a general comment, the Applicant respectfully emphasizes the enormous step forward achieved with the present invention. In addition, although the Applicant is not submitting a declaration at this point, the Applicant has submitted a Supplemental Information Disclosure Statement along with the response dated July 11, 2006 to the office action dated April 17, 2006. The Applicant respectfully requests that the Examiner note that the present invention has since been published in these well-known and respected journals. The invention has received notoriety as an important and novel discovery. The expert opinion clearly states that "the unique ability of the AKITA to precisely control inhaled volumes and flow rates may further provide for the aerosol to be more efficiently and reproducibly targeted to the regions of the lung most affected by the disease" [*Expert Opin. Drug Deliv.* (2005), vol. 2, iss. 4, p. 766, col. 2, line 16-20]. Furthermore, in "Lung Deposition after Electronically Breath-Controlled Inhalation and Manually Triggered Conventional Inhalation in Cystic Fibrosis Patients" [*Journal of Aerosol Medicine* (2005), vol. 18, no. 4, pp. 386-395] the improvement of the invention in comparison to manually triggered conventional inhalation devices, like the MDI suggested by Goodman *et al.*, is shown. This is evidence of the novelty of the invention and that it is widely regarded as being at the forefront of technology. Those of ordinary skill in the art recognize the importance of the invention. The Applicant believes that this evidence stands, on its own, without the need for a declaration. The Applicant would request the opportunity to file a declaration, if the Examiner is not convinced of the notoriety and import of publication within these specific journals regarding this invention.

Rejection under 35 U.S.C. §102

Claims 22, 25, 28-32, and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by Goodman (5,813,397). Applicant respectfully disagrees with the rejection.

Independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Goodman discloses an MDI (metered dose inhaler) which monitors breathing maneuvers. The MDI in Goodman is a manually triggered conventional inhalation device. The deposition of the drug in the lung only occurs in a subsequent step. In contrast, in the present invention, the inhalation maneuver is exactly predetermined and adjusted. This means that each individual patient has to inhale step by step the desired drug amount with his individual inhalation maneuver, which guarantees that the entire inhalation is successfully completed.

Goodman discloses a method of delivering aerosolized medicine in response to appropriate points in the patient's detected breath flow. Goodman also discloses detecting changes in the patient's breath patterns as a basis for adjusting the amount of medication to be delivered. Goodman also discloses containing operating parameters for different medications in the device. Goodman also discloses "selecting certain processing subroutines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions" (U.S. Patent No. 5,813,397, column 31, lines 3-8). Goodman does not disclose what "patient specific" requirements include.

Goodman only discloses storing medication parameters and adjusting administration based on breath patterns measured by the apparatus. Goodman does not disclose inserting a memory medium into the device or storing individual patient parameters on the memory medium before inhalation. Goodman also does not disclose adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition,

Goodman does not disclose evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Goodman does not disclose each and every element of Applicant's claim 25. Therefore, it is respectfully suggested that the rejection of independent claim 25 as being anticipated by Goodman is overcome. Claims 22, 28-31, and 35, as well as new claim 36, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 23, 24, 33, and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Wallace (6,024,089).

Applicants respectfully disagree, and believe the claims, as amended, are patentable over Goodman for the reasons given above in respect to the section 102 rejection of claim 25, from which claims 23, 24, 33, and 34 depend. The argument above as to the novelty of claim 25 is repeated here by reference.

Independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Goodman teaches a method of delivering aerosolized medicine in response to appropriate points in the patient's detected breath flow. Goodman also teaches detecting changes in the patient's breath patterns as a basis for adjusting the amount of medication to be delivered. Goodman also teaches containing operating parameters for different medications in the device.

Goodman also teaches "selecting certain processing subroutines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions" (U.S. Patent No. 5,813,397, column 31, lines 3-8). Goodman does not teach or suggest what "patient specific" requirements include.

Goodman only teaches storing medication parameters and adjusting administration based on breath patterns measured by the apparatus. Goodman does not teach or suggest inserting a memory medium into a device or storing individual patient parameters on the memory medium before inhalation. Goodman also does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Goodman does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Wallace does not provide what Goodman lacks. Wallace teaches a ventilation control system for controlling the ventilation of a patient. Wallace teaches "a digital processor, a touch sensitive display screen and entry means cooperating to provide a user-friendly graphic interface for use in setting up and carrying out a wide variety of respiratory therapies" (U.S. Patent No. 6,024,089, column 2, lines 63-65). Wallace does not teach or suggest inserting a memory medium into a device or storing individual patient parameters on the memory medium before inhalation. Wallace also does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Wallace does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Goodman in view of Wallace. Claims 23-24 and 33-34, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional

recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22, 24, 25, 28-32, 34, and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore *et al.* (5,931,160) in view of Rapoport *et al.* (5,490,502).

Independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Gilmore teaches a ventilation system and is as such distinct and remote from the subject matter of claim 25. Ventilation systems are substantially different in both purpose and function from inhalation systems. In the method of claim 25, not only are individual patient parameters stored on a memory medium, but the individual patient parameters are also thereafter evaluated, and the amount of therapeutic aerosol to be inhaled and applied to the lung is determined and can be exactly placed at the appropriate place in the lung by adjusting the respiratory flow or the tidal volume of the inhalation device based on the evaluated individual patient parameters. The deposition of the aerosol in the lung is highly related to and dependent on the inhalation maneuvers. An exact placement of the drug at the target position in the lung is not possible with Gilmore's ventilator control system, because the respiratory flow or the tidal volume that is used to transport the drug to the target position in the lung is not adjusted on the basis of the evaluated individual patient parameters. For example, for the patient to be treated it indeed makes a difference whether 2 mL containing 100 µg of drug are filled into the nebulizer for inhalation, and from 20 to 90 % of the drug may reach the lung depending on the inhalation maneuver. Therefore, according to the invention of claim 25, the required drug is exactly applied to the lung and not just approximately. This approach of claim 25 of adjusting a respiratory flow or tidal volume of the inhalation device based on the individual patient parameters is not only new over

the prior art, but has never been suggested before. Gilmore does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Gilmore does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Rapoport does not provide what Gilmore lacks. Rapoport relates to a completely different field from the present invention. Rapoport teaches adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea. The treatment of sleep apnea, i.e. the intermittent obstruction of the upper airway occurring during sleep, is in no way linked to the administering of a controlled inhalation of therapeutic aerosol for a patient during breathing maneuvers according to claim 25. Rapoport teaches basically using only two different pressures such that aerosol administration is not possible, because at the beginning of the inhalation a high flow, which decreases quickly, is present. Therefore, a large amount of drug would be applied to the throat but would not reach the lung. Rapoport does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Rapoport does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Gilmore and Rapoport, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully suggested that the rejection of independent claim 25 as being obvious over Gilmore in view of Rapoport is overcome. Claims 22, 24, 28-32, 34,and 35, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 23 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmore *et al.* (5,931,160) in view of Rapoport *et al.* (5,490,502) and further in view of Goodman (5,813,397).

Independent claim 25, upon which claims 23 and 33 depend, claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of

inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Gilmore teaches a ventilation system and is as such distinct and remote from the subject matter of claim 25. Ventilation systems are substantially different in both purpose and function from inhalation systems. In the method of claim 25, not only are individual patient parameters stored on a memory medium, but the individual patient parameters are also thereafter evaluated, and the amount of therapeutic aerosol to be inhaled and applied to the lung is determined and can be exactly placed at the appropriate place in the lung by adjusting the respiratory flow or the tidal volume of the inhalation device based on the evaluated individual patient parameters. The deposition of the aerosol in the lung is highly related to and dependent on the inhalation maneuvers. An exact placement of the drug at the target position in the lung is not possible with Gilmore's ventilator control system, because the respiratory flow or the tidal volume that is used to transport the drug to the target position in the lung is not adjusted on the basis of the evaluated individual patient parameters. For example, for the patient to be treated it indeed makes a difference whether 2 mL containing 100 µg of drug are filled into the nebulizer for inhalation, and from 20 to 90 % of the drug may reach the lung depending on the inhalation maneuver. Therefore, according to the invention of claim 25, the required drug is exactly applied to the lung and not just approximately. This approach of claim 25 of adjusting a respiratory flow or tidal volume of the inhalation device based on the individual patient parameters is not only new over the prior art, but has never been suggested before. Gilmore does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Gilmore does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Rapoport does not provide what Gilmore lacks. Rapoport relates to a completely different field from the present invention. Rapoport teaches adjusting the positive airway pressure of a patient to an optimum value in the treatment of obstructive sleep apnea. The treatment of sleep apnea, i.e. the intermittent obstruction of the upper airway occurring during sleep, is in no way linked to the administering of a controlled inhalation of therapeutic aerosol for a patient during breathing maneuvers according to claim 25. Rapoport teaches basically using only two different pressures such that aerosol administration is not possible, because at the beginning of the inhalation a high flow, which decreases quickly, is present. Therefore, a large amount of drug would be applied to the throat but would not reach the lung. Rapoport does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Rapoport does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Goodman does not provide what Gilmore and Rapoport lack. Goodman teaches a method of delivering aerosolized medicine in response to appropriate points in the patient's detected breath flow. Goodman also teaches detecting changes in the patient's breath patterns as a basis for adjusting the amount of medication to be delivered. Goodman also teaches containing operating parameters for different medications in the device. Goodman also teaches "selecting certain processing subroutines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions" (U.S. Patent No. 5,813,397, column 31, lines 3-8). Goodman does not teach or suggest what "patient specific" requirements include.

Goodman only teaches storing medication parameters and adjusting administration based on breath patterns measured by the apparatus. Goodman does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Goodman does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Gilmore, Rapoport, and Goodman, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Gilmore in view of Rapoport and further in view of Goodman. Claims 23 and 33, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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